

REMARKS

Applicants gratefully acknowledge Examiner's withdrawal of rejections under 35 U.S.C. § 102. Applicants also gratefully acknowledge Examiner's withdrawal of the 35 U.S.C. § 112 rejection of claims 22-29 as being indefinite in the recitation of "method of treating."

Double Patenting

Claims 1-11 and 22-29 remain rejected as unpatentable over issued claims 1-18 of U.S. patent 5,965,130 and issued claims 1-10 of U.S. patent 5,562,902 under the obviousness-type double patenting doctrine. Applicants remain ready to submit a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) upon an indication by the Examiner that all other rejections are withdrawn.

35 U.S.C. § 112, first paragraph

Claims 1-11 and 22-29 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants traverse.

The Examiner states that applicants are required to demonstrate clear support for the phrase "wherein the mammal has metastatic lymphoma." As discussed below, applicants believe that there is full support in the specification for this phrase.

Applicants' specification states that lymphoma, among certain other types of cancer, is "particularly prone to metastasize" (page 2, lines 6-8). The specification also set forth the problem that "existing systemic treatments have, quite often, proven to have little effect on micrometastases already residing in remote organs . . . and they are not very effective in preventing dissemination of the tumor to other tissues" (page 3, lines 6-10).

The specification then describes the use of IVIG to "act as anti-metastatic agents resulting in the reduction of tumor colony number" as one aspect of the claimed invention (page 7, lines 4-6). Examples 1-5, demonstrating the effectiveness of the claimed invention, were carried out in mouse models of metastatic cancer. These examples, on pages 10-15 of the specification, describe systemic infusion (either intravenous or intraperitoneal) of melanoma or sarcoma cells into mice such that metastasis is the control state. In this model, the cells of the infusate are micrometastases that, at the time of injection, are not localized to any one point in the body and may therefore properly be described as metastatic.

This comports with the definition of "metastasis" found in the specification as "the transfer of malignant tumor cells, or neoplasm, via the circulatory or lymphatic systems or via natural body cavities, usually from the primary focus of neoplasia to a distant site in the body, and subsequent development of secondary tumors or colonies in the new location (page 4, lines 22-27). That is precisely the course of events in the mouse tumor model, where development of secondary tumors is measured subsequent to injection of tumor cells into the circulatory system or body cavity.

Examples 6 and 7 of the specification further support the use of IVIG in patients with metastatic disease. Example 6 describes regimens of treatment that “may be varied according to the patient’s age and physical condition, and the severity of the disease” (page 15, lines 25-27). This allows for the treatment of patients with advanced metastatic cancer, as is discussed in Example 7.

Example 7 describes the administration of IVIG to a human patient with multiple cancerous lesions in the liver and lungs, and a lesion in the spleen. After discovery of this metastatic disease, treatment with IVIG was initiated (page 16, lines 3-29).

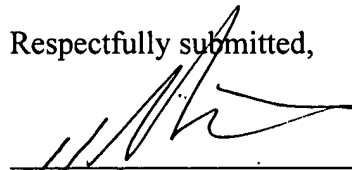
While none of the above-mentioned examples involved lymphoma, applicants believe that those examples, together with Example 8 (page 17, line 1 through page 19, line 2), which shows a dose-dependent inhibition of proliferation of T-cell lymphoma cells in culture by IVIG, fully enable one of skill in the art to practice the claimed invention.

With respect to the need for one of skill in the art to make a determination of whether metastatic disease is present, applicants respectfully submit that such a determination is routinely done at the diagnosis stage by the examining physician. Indeed, that was the case in Example 7 of the specification.

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Based on the above remarks, applicant requests that the Examiner
withdraw the rejection of claims 1-11 and 22-29 under 35 U.S.C. § 112.

Respectfully submitted,



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